

## Institutional Review Board

## Quality Improvement Proposal Form

#  INSTRUCTIONS

Quality Improvement (QI) projects consist of activities that are undertaken to measure the effectiveness of standard accepted processes, programs, or services. The goal of a QI project is to improve performance of institutional practices by using a systematic approach guided by data to improve the quality and safety of healthcare delivery (Hall & Roussel, 2022). Quality improvement projects are not designed to contribute to generalizable knowledge and cannot expose individuals to any additional risks. If you believe that your project meets this definition, please follow the below instructions for submission.

**The Edgewood University IRB will review QI projects to make a determination as to whether the project meets all the requirements for a QI project. IRB oversight may be required in some NON-research projects, for the protection of participants and/or personal information.**

Proposals are reviewed on a rolling basis; there is no deadline for submission. Upon submission, the IRB Administrator completes a brief pre-review (within the first three days) to determine if the documentation provided in the application is sufficient to be reviewed. If the IRB determines that the proposal is incomplete the application will be returned to the investigator with a request for additional information.

The application form utilizes a series of embedded text fields. When completing sections of the form that require typewritten responses, place the cursor over the shaded areas, left click, and begin entering the requested information. **When addressing portions of the form that require a “checked box” response, place the cursor over the desired box, double left-click, select “checked” under the heading “default value,” and select “ok.”**

**If you have any questions or need assistance completing this application,**

**please contact David Lambert at** **lambert@edgewood.edu****.**

#  GENERAL INFORMATION

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| **Project Title:** |
| **Principal Investigator/Project Manager:**       |
| **Department/School or Affiliation:**       |
| **Email Address:**       | **Phone:**       |
| **Proposed Start Date:**      **Funding Source (if applicable):**       | **Anticipated Completion Date:**       |
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| **Project Manager Status:**  |
| [ ]  Full-time Faculty [ ]  Adjunct or Part-time Faculty | [ ]  Undergraduate Student[ ]  Master’s Student |
| [ ]  Staff  | [ ]  Doctoral Student |

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| **Type of Project:** |
| [ ]  DNP Project | [ ]  Class project—Please specify class: |       |
| [ ]  Thesis  | [ ]  Dissertation | [ ]  Other. Please specify: |       |

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| **Funding Status:** |
|  [ ]  Externally Funded | [ ]  Internally Funded | [ ]  Grant Application | [ ]  Not Funded |

**Publication/Presentation:**Will the results from the project be published/presented outside of Edgewood University? [ ]  Yes [ ]  NoWill the results from the project be published/presented outside of Edgewood University? [ ]  Yes [ ]  No**Project Manager Assurance Statement**By signing this form, **I, the Project Manager,** certify that:1. The information provided in this application is correct;
2. I have read and understand Edgewood University policies regarding protection of human participants;
3. I will not begin work on this project until the notification of approval is received;
4. I will provide the Completion Certificate for the CITI Social & Behavioral Research-Basic Course training module (or equivalent).
5. I take responsibility for the project design, and will make best efforts to ensure all personnel engaged in the project are compliant with the requirements of the Edgewood University IRB;
6. I will be available to answer questions from the IRB regarding the application;
7. I will seek approval from the IRB in advance of implementing changes (*Change to Approved Research Form*);
8. I will immediately report to the IRB any serious adverse reactions or unexpected effects on participants;
9. If I continue my QI project beyond the one-year approval from the IRB I agree to submit a status report for continuation review 30 days prior to expiration of approval (*Continuing Review Form*);
10. **For ALL student projects, your Faculty Advisor has thoroughly reviewed the application, received ethics training, provided signatory testimony that the application exhibits clarity and completeness. Adequate supervision from the advisor (or designated individual) will be provided to students conducting research.**

**PI Name:**       **Date:**      By entering my name above I certify that I am in compliance with the Project Manager Assurance Statement outlined above.**For Students**The name of your Edgewood University **faculty advisor is required in the box below. BOTH YOU AND YOUR ADVISOR ARE REQUIRED TO “SIGN”** **THE QUALITY IMPROVEMENT PROJECT IN IRBNET.** In signing the research project in IRBNet, the faculty advisor certifies that they have reviewed the QI Project, approved the scientific and ethical aspects of the project, and proofread this document. The faculty advisor will supervise all compliance with ethical guidelines**.** ***Make sure to share your proposal with your Advisor, and that your Advisor has provided their signature prior to submission to IRBNet.***

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| **Name of Faculty Project Advisor:**       | **Phone:**       |
| **Department/School or Affiliation:**       | **Email:**       |

**My Faculty Project Advisor has provided me with a copy of their Ethics Tutorial Completion Certificate: [ ]  Yes [ ]  No****Additional Investigators**Provide the names, titles, and affiliations of all students AND advisors involved in this QI project. **IRB training is required for all students and advisors.** If needed, Training Completion Certificates can be obtained by completing the CITI Online Tutorial. You can register and complete the tutorial at <https://about.citiprogram.org/en/homepage/>***Make sure you have electronic signatures for all investigators included in your submission to IRBNet.***

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| **Name** | **Institution** | **Phone Number** | **Completed Tutorial** |
|  |  |  | **[ ]  Yes** |
|  |  |  | **[ ]  Yes** |

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#  PRELIMINARY CHECKLIST

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| **Instructions:** Answer **YES** or **NO** to each of the following statements about QI projects. | **Y Yes** | **N No** |
| 1. The QI project has been shared with your faculty project advisor in IRBNet, and your faculty advisor has signed the QI project and has provided a copy of their CITI Completion Certificate to upload.
 | [ ]  | [ ]  |
| 1. The QI project is conducted under the direction of a site supervisor who has the authority to, if appropriate, impose a corrective plan based on the outcomes of the project.
 | [ ]  | [ ]  |
| 1. The risk to patients/participants is no greater than what is involved in the care they are already receiving.
 | [ ]  | [ ]  |
| 1. The project does not require access to patient or employee records beyond your scope of practice or responsibility. If records are beyond the scope, then a site supervisor has provided documentation allowing access to the records in accordance to the site policies.
 | [ ]  | [ ]  |
| 1. The site sponsor (hospital, clinic, care group) has provided signed documentation to the IRB acknowledging support for the QI project, including providing permission for the access necessary documentation to complete the QI project (i.e., not independent research reliant on the voluntary participation of colleagues, students and/or patients).
 | [ ]  | [ ]  |

#  INTENT AND PURPOSE

What is the intent and purpose of your project? Please check all that apply:

[ ]  To contribute to generalizable knowledge (e.g. testing a hypothesis, establish a registry or database from which a hypothesis will be tested).

[ ]  To contribute to the knowledge base of a discipline (e.g. establish innovative clinical practice standards where existing ones need updating).

[ ]  To improve the process/delivery of care within a specific health care setting while decreasing inefficiency (e.g. measure variation from or improve adherence with standard practice, measure satisfaction with standard practice, compare a program/process system with an established set of standards).

[ ]  Other:

Please provide a **brief** statement, in lay terminology, outlining the intent and purpose of this project (i.e. what are the goals and objectives of the project?):

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#  METHODS

Describe in detail the design of your project, as well as the conceptual framework and methods that you will use. Please specify all sources of data you will use (e.g. charts, surveys, etc.). Be sure to upload a copy of all materials.

Explain where the project will be conducted, the data collection methods used, precisely what participants will do or have done to them, and the amount of time of active involvement for the participants. If applicable, outline the technical assistance available, monitoring techniques to be used, and planned safeguards in case of emergencies or unusual events.

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Please check all statements that apply to the methods you will utilize:

[ ]  We will be implementing an evidence-based intervention that has been previously established/published.

[ ]  We will be implementing a novel intervention that has not yet been reported in the literature.

[ ]  We will only be evaluating an existing program, intervention and/or procedure.

[ ]  Other:

#  POPULATION

Will the focus of the QI project be solely on improving program efficiency and effectiveness, or will it also involve the evaluation of any of the groups listed below? **NOTE**: If data/information will be collected about a member of these groups, regardless of whether they will be evaluated, please check the corresponding box. Another thought that I have is to rephrase or broaden the question so that we could also add an option that explicitly states improving process effectiveness.

[ ]  Improving efficiency and effectiveness of program processes (not with patients/human participants).

[ ]  Medical facility patients (e.g. hospitals, clinics, etc.)

[ ]  Edgewood University Students or Employees

[ ]  Other:

Please provide a brief description:

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#  BENEFIT

Who will benefit from this activity? Please check all that apply:

[ ]  The program/department under evaluation would benefit from the project. If so, please describe:

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[ ]  The most significant benefit from the project is societal or to the greater medical community (i.e. in developing new or advancing existing general knowledge)? If so, please describe:

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#  SAFEGUARDING CONFIDENTIALITY

Describe plans to protect the participants’ identities as well as the confidentiality of the data. Explain the mechanisms that have been devised to safeguard confidentiality, (e.g., the use of numbering or code systems, safely locked files in password-protected computers in private offices). Describe who will have access to the data and plans for final disposition or destruction of such records.

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Resource:

Hall, H.R., & Roussel, L.A. (2022). *Evidence-Based Practice: An Integrative Approach to Research, Administration, and Practice* (3rd ed.). Jones & Bartlett Learning.